REMARKS

Claims 1-14 and 16-28 are currently pending in the application. Claims 1, 22, 23, and 26 are in independent form.

Claims 1-5 and 26-28 stand rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 6,045,532 to Eggers, et al. Specifically, the Office Action holds that Eggers, et al. discloses a neurosurgical catheter with an external diameter not more than 0.5 mm and a hub (614) that represents a fitting and has a stop surface with the catheter. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Eggers, et al., as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action asserts that Eggers, et al. discloses a single fine tube. Upon closer look, while the Eggers, et al. device can have a single fluid delivery lumen (see lines 1-13 of column 25), the Eggers, et al. device also always includes multiple tubular electrodes with associated insulators. Therefore, Eggers, et al. does not disclose a catheter having a ***single fine tube*** arranged for insertion into the brain parenchyma as required by the presently claimed invention. Claim 26 has been

amended to require that the fine tube is a single fine tube, as previously amended in claim 1.

With regards to the fitment (614), Eggers, et al. describes this element as providing the fluidic and electrical connections between the multiple lumens and wires of the catheter (460) and the associated tubes and electrical leads. The fitment (614) is attached to the proximal end of the catheter (460) and appears to have a larger radius than the catheter. While the fitment (614) of Eggers, et al. can be called a "hub" because it acts to link the various supply tubes and leads to the relevant lumens and electrodes of the catheter, and has a protruding surface which has a similar structure to the stop surface of the hub of the present invention, there is no disclosure in Eggers, et al. of the fitment (614) being used to set the depth of catheter insertion. In other words, the fitment (614) may have a similar structure to the hub of the present invention, but it does not perform any kind of depth setting function. The claims of the present invention have been amended to include this requirement of the stop surface maintaining a distal end of the catheter accurately located at a target in the brain parenchyma of the patient. Support for this amendment can be found in the following paragraph:

[0015] Preferably, the head of the guide tube includes an externally threaded surface for engagement with the skull of the patient via an acrylic cement. According to a preferred embodiment, the head includes a slotted dome structure, and ***the catheter has a hub having a stop at one end*** which abuts the dome structure once the fine tube has been inserted into the guide tube. The slot is preferably shaped such that, as the catheter is bent over in the slot, it resists kinking. The domed structure is preferably shaped such that, as the catheter is bent over in the slot with the stop abutting the domed surface, ***the distal end of the catheter will remain accurately located at its target***. Reference is made to GB-A-2357700 which discloses a guide

tube with a head having a domed structure, the disclosure of which is incorporated herein by reference.

In other words, by using the hub with the stop surface, the distal end of the catheter enters the parenchyma and travels only a certain depth to a specific target, at which point it is stopped and held in place by the stop surface and hub.

Therefore, since Eggers, et al. does not disclose a neurosurgical catheter with a single fine tube (as set forth in independent claims 1 and 26) and hub (as set forth in independent claim 1), the claims are patentable over Eggers, et al. and reconsideration of the rejection is respectfully requested.

Claims 1-12, 16, and 26-28 stand rejected under 35 U.S.C. § 102(e), as being anticipated by U.S. Patent No. 6,517,550 to Konya, et al. Specifically, the Office Action holds that Konya, et al. discloses a neurosurgical catheter with an external diameter not more than 0.5 mm connected to a hub (24) at the stop surface. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Konya, et al., as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The device described in Konya, et al. is a snare or retrieval device for removing foreign articles from the body. As noted in the Office Action, this is described as comprising a catheter 20 that can have an outer diameter as small as 1.5Fr (0.5 mm); see lines 49-62 of column 13. The Office Action further indicates that the catheter comprises a hub 24 at its proximal end, this is shown in Figure 12 and is basically a change in diameter of the device. The Office Action also indicates

that Konya, et al. discloses a connector tube 27 as shown in Figure 17. A fluid can be passed through the device in use (e.g. see lines 32-35 of column 18).

Konya, et al. discloses an intravascular catheter that has a length of a meter or more (see lines 49-62 of column 13) and is therefore ***not suitable for insertion into the brain parenchyma*** as recited in independent claims 1 and 26 of the present invention.

Also similar to Eggers, et al., Konya, et al. could be said to include a hub with a stop surface in the broadest sense, but there is absolutely no disclosure in Konya, et al. of a hub with a stop surface for setting the depth of catheter insertion.

Therefore, since Konya, et al. does not disclose a catheter that can be used for insertion into the brain parenchyma or a hub that sets a depth of catheter insertion as set forth in the presently pending independent claims, the claims are patentable over Konya, et al. and reconsideration of the rejection is respectfully requested.

Claims 1-14 and 16-28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,902,569 to Parmer, et al. and U.S. Patent No. 6,591,472 to Noone, et al. Specifically, the Office Action holds that Parmer, et al. discloses the catheter as claimed but fails to disclose the outer diameter being not more than 0.5 mm. The Office Action holds that Noone, et al. discloses that it is well known to uses neurosurgical catheters that have small outer diameters ranging from 1 to 3 French, and therefore, it would be obvious for one skilled in the art to make the device of Parmer, et al. with a diameter as taught in Noone, et al. Reconsideration of the rejection under 35 U.S.C. §103(a), as being unpatentable over Parmer, et al. and Noone, et al. is respectfully requested.

> "Any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed"; however, that reason must be present for the combination to be obvious. *KSR Intern Co. v. Teleflex*, 127 S. Ct. 1727, 1742, U.S. (2007). This requirement was confirmed in *Takeda Chem. Indust., et al. v. Alphapharm*, No. 06-1329 (Fed. Cir. 2007).
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> "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit." MPEP Section 2143.
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> "The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art." *KSR International Co. v. Teleflex Inc.*, 83 UDPQ2d 1385, 1395 (2007) and MPEP Section 2143.

Parmer does disclose inserting a catheter (having an outer diameter of 1 mm or more) into the brain parenchyma. In particular, Parmer describes a guide device (e.g. see Figure 3, column 9, line 39 to column 10, line 32) that includes a base 210 that is attached to a hole formed in the skull, a moveable member 220 (e.g. a ball with a channel through it), an elongate guide stem 240 and a locking member 230. The moveable member is aligned using positioning stem 400 shown in Figure 3 and is then locked in place by the locking member 230. Once locked, an instrument can be guided to the required target (column 13, lines 49-50). As shown in Figure 8 of Parmer (see also column 13, line 51 to column 14, line 20), the upper parts of the guide device can be removed over an inserted flexible instrument 229 (e.g. a catheter). This leaves the flexible instrument 229 and base 210 as shown in Figure 8a. A cap 310 can then be used to engage the base 210 and hold the flexible

instrument in place. Such a cap is shown in Figure 9 (see column 14, lines 22-37). The proximal end of the flexible instrument (i.e. the bit protruding the skull) can then be tunneled subcutaneously. The catheters described in Parmer are merely flexible plastic tubes. The tubes are held in place using a clip on cap that is introduced after insertion. It can thus be seen that Parmer does not teach providing a catheter comprising a hub and a stop surface.

The Office Action argues that the terms catheter and surgical instrument are used interchangeably throughout the Parmer specification; this is incorrect because Parmer actually describes (e.g. see lines 5-10 of column 19) a catheter as being ***one example*** of a surgical instrument (another example mentioned is a needle). The Office Action then refers to Parmer as disclosing a hub (220) with a stop surface. The item 220 that is termed the hub by the Office Action is not a part of the catheter but is the moveable member 220 of the trajectory guide 200 (i.e. the ball which is aligned and then used to guide instruments into the brain). As stated above, Parmer only discloses catheters comprising flexible plastic tubes without any hub or stop surface.

Noone does describe catheters having an OD from 0.33 mm to 1.0 mm, but these are ***intravascular*** catheters. The Noone catheters are not intraparenchymal catheters of the type described in Parmer and as claimed in the present invention.

It is therefore submitted that neither Parmer or Noone, whether read alone or in combination, teach the structure of the catheter that is defined in claims 1 and 26 of the present application. Furthermore, there are no teachings in Parmer or Noone related to a guide tube structure that is inserted into brain parenchyma recited in claims 22 and 23. The only guide element used in Parmer is always located external to the skull.

Since neither the cited references alone or in combination with knowledge in the art suggest the currently claimed invention, it is consequently respectfully submitted that the claims are clearly patentable over the combination, even if the combination were to be applied in opposition to applicable law, and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above, and the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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